K001523

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## SUMMARY OF SAFETY AND EFFECTIVENESS

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|---|---|
| **NAME OF FIRM:** | DePuy Orthopaedics, Inc.<br>700 Orthopaedic Drive<br>Warsaw, Indiana 46581-0988 |
| **510(k) CONTACT:** | Cheryl Hastings<br>Director, Regulatory Affairs |
| **TRADE NAME:** | Ultima® Metal-On-Metal Acetabular Cup |
| **COMMON NAME:** | Total Hip Replacement System |
| **CLASSIFICATION:** | 888.3330: Hip joint, metal/metal semi-constrained, with an uncemented acetabular component, prosthesis. Class III |
| **DEVICE PRODUCT CODE:** | 87 ~~JDM~~ KWA |
| **SUBSTANTIALLY EQUIVALENT DEVICES:** | ♦ ZTT II Acetabular Cup System (K951000)<br>♦ Sulzer Orthopedics Inc. Inter-Op Metasul Acetabular System (K974728)<br>♦ McKee-Farrar Metal-On-Metal Hip (pre-amendment)<br>♦ Ring Metal-On-Metal Hip (pre-amendment) |

**DEVICE DESCRIPTION AND INTENDED USE:**
The Ultima Metal-On-Metal (MOM) Acetabular Cup is comprised of a metal shell and a metal liner. The outer acetabular cup is a near-hemispherical stepped and porous-coated shell with three dome screw holes, an apical hole used for visualization, and a peripheral female taper. The liner is offered in both standard (neutral) and augmented (10° lip) forms and has a 28mm inner diameter. The MOM liner is mechanically locked with the shell via a taper junction, and articulates with commercially available prosthetic femoral heads.

It is indicated for use as the acetabular component in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and non-union of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, *protrusio acetabuli*, slipped capital femoral epiphysis

and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Ultima Metal-On-Metal Acetabular Cup is intended for use with DePuy S-ROM and PFC 28mm diameter Co-Cr-Mo femoral heads only.

**BASIS OF SUBSTANTIAL EQUIVALENCE:**

The Ultima Metal-On-Metal Acetabular Cup is equivalent to the ZTT II Acetabular Cup in that they have the same intended use and the same basic design. The differences between the two designs are that the Ultima MOM Cup has a metal insert and a taper-lock locking mechanism, whereas the ZTT II Cup has a polyethylene insert which locks into the metal shell via polyethylene lugs on the insert that dial into slots in the shell.

Clinical data collected from two prospective, multi-center studies showed that at 24(+) month follow-up, mean total Harris Hip Scores and mean pain Harris Hip Scores for the metal-on-metal cases (using the Ultima Metal-On-Metal Acetabular Cup) were significantly higher than those for metal-on-polyethylene cases (using the ZTT II Acetabular Cup). Mean function scores, radiographic parameters and complication rates between the two groups were similar.

The Ultima Metal-On-Metal Acetabular Cup is also substantially equivalent to the Sulzer Inter-Op Metasul Acetabular System. Both are metal-on-metal acetabular cup systems, intended for cementless fixation. The liner of the Ultima MOM Cup is composed only of wrought Co-Cr-Mo. The liner of the Inter-Op Metasul Cup is composed of polyethylene with a wrought forged Co-Cr-Mo inlay. This creates a metal-polyethylene-metal "sandwich" when the liner is assembled with a metal shell.

The Ultima Metal-On-Metal Acetabular Cup is also substantially equivalent in basic design and intended use to several pre-amendment metal-on-metal hip systems. Of these, the McKee-Farrar and the Ring are probably the most widely known and documented. The McKee-Farrar and Ring metal-on-metal hips were implanted in the 1950's through the 1970's with moderate clinical success and are the fore-runners of today's metal-on-metal hip designs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2000

Ms. Cheryl Hastings
Director, Regulatory Affairs
DePuy, Inc.
P.O. Box 988
700 Orthopedic Drive
Warsaw, Indiana 46581-0988

Re: K001523
Trade Name: Ultima® Metal-On-Metal Acetabular Cup
Regulatory Class: III
Product Code: KWA
Dated: May 12, 2000
Received: May 16, 2000

Dear Ms. Hastings:

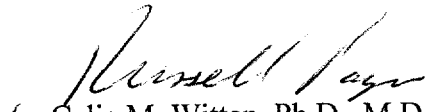
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K001523

Device Name DePuy Orthopaedics Ultima® Metal-On-Metal Acetabular Cup

Indications for Use:
The Ultima® Metal-On-Metal Acetabular Cup is indicated for use as the acetabular component in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and non-union of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, *protrusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Ultima Metal-On-Metal Acetabular Cup is intended for use with DePuy S-ROM and PFC 28mm diameter Co-Cr-Mo femoral heads only.

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Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001523

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-The Counter Use No